

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-314V

UNPUBLISHED

RONDA BRUM SMITH,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 26, 2022

Special Processing Unit (SPU);
Findings of Fact; Onset; Tetanus
Diphtheria acellular Pertussis (Tdap)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA)

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On February 28, 2019, Ronda Smith filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that a tetanus diphtheria acellular pertussis (“Tdap” or “tetanus”) vaccine she received on February 29, 2016, caused her to suffer the Table injury of “Shoulder Injury Related to Vaccine Administration” (“SIRVA”). Petition at 1, ECF No. 1; Amended Petition filed July 22, 2019, ECF No. 12. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the onset of Petitioner's SIRVA more likely than not occurred within 48 hours of vaccination.

I. Relevant Procedural History

Respondent filed his Rule 4(c) Report in April 2020, a little more than a year after the claim's initiation. ECF No. 25. Respondent specifically maintained therein that the evidence preponderated against a finding that the onset of Petitioner's shoulder pain occurred within 48 hours of her vaccination as required by the Vaccine Injury Table. *Id.* at 6-8 (citing 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI)). Respondent further argued that Petitioner had not provided evidence sufficient to establish causation-in-fact under the relevant standard. *Id.* at 8-9.

I subsequently ordered Petitioner to file any additional evidence in support of her claim she could identify. In response, Petitioner filed sworn declarations from 12 individuals asserting knowledge in regard to the onset of her injury, among other things. Exhibits 25-38. I convened a status conference on January 27, 2021, and strongly encouraged the parties to settle this case given the significant litigative risk that existed on both sides. ECF No. 33. Subsequently, Petitioner provided a demand to Respondent, but Respondent advised that his position was unchanged and that he was "not interested in [an] informal resolution" of this case. ECF No. 34.

Accordingly, the parties proceeded to brief the issue of onset for my consideration. On April 5, 2021, Petitioner filed her brief, ECF No. 36; Respondent filed a brief in response on May 20, 2021, ECF No. 38; and Petitioner filed a brief in reply on May 27, 2021, ECF No. 39. This matter is ripe for adjudication.

II. Issue

At issue is whether Petitioner's first post-vaccination symptom or manifestation of onset (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) I.C & II.C. (Tdap vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation,

and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly

recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also *Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record to include all medical records, affidavits or declarations, Respondent’s Rule 4 report, the parties’ briefs, and additional evidence filed. Specifically, I note the following facts from the medical record:

- Petitioner established care with a new physician, Camellia Babaie, M.D., on February 29, 2016. Ex. 11 at 10-13. At that visit, Petitioner received a Tdap vaccination in her left deltoid. Ex. 10 at 1.
- Petitioner returned to see Dr. Babaie on March 15, 2016, to follow-up regarding her lab results. Ex. 11 at 33. The record from March 15, 2016 contains no mention of shoulder pain or Petitioner’s Tdap vaccination.
- On April 15, 2016, Petitioner was seen again by Dr. Babaie for a complaint of “left shoulder pain x 3 weeks.”³ Noted the onset when waking one morning. States it hurts to lift her arm at the shoulder, limit[s] her motions. . . . Does not recall any particular trauma.” Ex. 11 at 38. Dr. Babaie assessed Petitioner with left shoulder pain, specifically indicating “possible left shoulder impingement syndrome vs rotator cuff tear” and advised Petitioner to take ibuprofen as needed. *Id.* at 40.
- Petitioner underwent an MRI on April 26, 2016, Ex. 11 at 42-43, and returned to see Dr. Babaie on April 29, 2016, *Id.* at 44. Petitioner complained that her shoulder pain had become more severe “after reaching behind her for her sunhat” and experiencing “searing pain radiating from her

³ Three weeks prior to April 15, 2016 would have been approximately March 25, 2016.

shoulder.” *Id.* at 44. Petitioner was assessed with a labral shoulder tear. *Id.* at 45.

- Petitioner was seen again by Dr. Babaie for her shoulder injury on May 16 and May 31, 2016, and had a second MRI on May 25, 2016. These appointments do not discuss the initial onset of Petitioner’s injury. Ex. 11 at 47-54. However, on May 31, 2016, Dr. Babaie referred Petitioner to see an orthopedist for further evaluation and management of her shoulder injury. *Id.* at 53-54.
- Prior to seeing orthopedist, Robert Mazurek, M.D, Petitioner completed a patient history form dated June 8, 2016. Ex. 13 at 13. The form asks if the “problem” was due to an injury. *Id.* Petitioner indicated that she was “not sure orig[inally] then later yes.” *Id.* The form also requests the patient indicate how the injury happened. Petitioner indicated: “2/29/2016 Had Tdap booster – shoulder/arm became extremely sore + limited ROM. 4/27/16 Jerked both arms over head to catch hat flying off + hurt arm/shoulder badly. Shoulder became even more sore w[ith] waves of pain down arm, limited ROM etc.” *Id.*
- Petitioner was first seen by Dr. Mazurek on June 9, 2016. Dr. Mazurek’s record of this visit notes that Petitioner had “a several month history of left shoulder pain and loss of function [which] she states it all started with an intramuscular injection [and] then she had a reinjury trying to catch her ha[t] as the wind blew [it] off her head.” Ex. 13 at 3.
- Petitioner was referred to physical therapy and underwent an initial examination on June 17, 2016. The intake examination record provides a history that Petitioner received a “Tetanus booster in Feb[uary] – L[eft] shoulder became very painful – couldn’t move – started improving – then wind blew hat off – made quick grab – felt tearing in shoulder – severe pain since.” Ex. 14 at 6.
- Shortly thereafter, in July 2016, Petitioner sought chiropractic treatment for her shoulder pain and completed associated patient intake information forms. Under the “Patient Condition” section of these forms Petitioner reported complaints of “shoulder pain, weakness, limited range of motion.” Ex. 15 at 8. Petitioner recorded February 29, 2016 as the date she “first noticed symptoms” in regard to her complaints and when asked to describe how the symptoms began Petitioner reported as follows: “2/29/16 received

booster tetanus shot + symptoms began. Then on 4/27/16 hat flew off + tried to catch – symptoms increased.” Ex. 15 at 8.

- Petitioner underwent her first chiropractic treatment with Aaron Ayala, D.C. on July 5, 2016. Dr. Ayala indicates that Petitioner presented “with a new complaint of left anterior shoulder discomfort that she says began since Tdap vaccination.” Ex. 15 at 11.
- On November 7, 2016, Petitioner sought treatment from a new orthopedist, Sumit Rana, M.D. for her left shoulder pain. Ex. 16 at 2. Dr. Rana’s history of Petitioner’s left shoulder pain indicates that “[o]n 2/29/16 patient received Tdap vaccine and shoulder became painful and frozen. Patient jerked arm to catch hat on 4/27/16 and caused extreme pain in left shoulder. The problem is improving especially with the active release from the chiropractor.” *Id.*
- Petitioner began a second round of physical therapy for her left shoulder with a new provider on April 17, 2017. Ex. 17 at 4. The reason for the referral indicates the “onset [of shoulder pain] was 2/29/16 shortly after she received a tetanus booster update. The shot hurt at the time of inject[ion] and then she had a strong reaction with swelling.” *Id.*

As the preceding facts demonstrate, the records corresponding to Petitioner’s March 15, 2016 visit with Dr. Babaie – the first after vaccination - fail to document any report of shoulder pain. In addition, the records from Petitioner’s subsequent April 15, 2016 visit with Dr. Babaie document a report of shoulder pain for three weeks – placing onset in late March, nearly a month after Petitioner’s vaccination. And the first record setting forth Table onset is from June 2016 – more than three months post-vaccination, and despite prior opportunities to seek treatment for alleged pain. Based on these records alone, it could reasonably be concluded that onset occurred *more than* 48 hours post-vaccination.

On the other hand, Petitioner has filed numerous sworn declarations, including her own, in support of her position that the onset of her shoulder pain began within 48 hours of her vaccination. Petitioner’s declaration describes the administration of a Tdap vaccination in her left shoulder, and a flu vaccination in her right shoulder, on February 29, 2016. Ex. 1, ¶ 5. Petitioner indicates that she observed that her left shoulder “felt strange almost immediately,” and that “[b]y the time I walked to my car my left shoulder was already hurting.” *Id.*, ¶ 6. Petitioner adds that she telephoned Dr. Babaie’s office a

day or two later, since her pain continued, but was advised by the nurse answering the phone to “give it time” and her “pain would go away.” *Id.*, ¶ 7.

Thereafter, at a follow-up appointment with Dr. Babaie on March 15, 2016, to discuss her lab work, Petitioner asserts that she reported to Dr. Babaie that she had experienced shoulder pain since immediately following her tetanus shot. Ex. 1, ¶ 8. But she maintains that Dr. Babaie was not concerned with her complaint, informing her that she should give it more time and “the soreness was just due to the shot.” *Id.* Then, at the April 15th return visit, Dr. Babaie told her that “a vaccine could not cause a shoulder injury,” asked whether she could have injured her shoulder another way, adding that many people with “frozen shoulder just woke up with it like that one day.” *Id.*, ¶ 9. Petitioner also contests the accuracy of the record’s note that she “woke up” with the injury. *Id.*, ¶ 10.

Besides her own declaration, Petitioner has also offered sworn declarations from her family, friends, and acquaintances, all of whom recall Petitioner experiencing shoulder pain and describing the onset of the pain as closely following her vaccination. Exs. 26-27, 29-37. Several of the declarants are family members who indicate that they saw Petitioner the day of her February 29, 2016 vaccination, and specifically recall her immediate complaints of shoulder pain from the shot. Exs. 26-27, 31, 33.⁴

The declarations discussed above would not have been sufficient *alone* to overcome the contemporaneous medical records. However, the witness statements corroborate, and are consistent with, the contemporaneous medical records from the five other treaters (aside from Dr. Babaie).

The Vaccine Act specifically contemplates that in some cases a special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table *even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.*” Section 13(b)(2)(emphasis added). The Act elaborates that “[s]uch a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

⁴ I also note that Petitioner has filed purported text messages and personal notes memorializing her February 29, March 15, April 15, and April 29, 2016 medical appointments in support of a 48-hour onset. Exs. 25, 28. Petitioner maintains in her brief that it is her “custom and habit” to make notes about what was discussed following her medical appointments and describes the text messages as communications with her daughter from May 29, 2016 documenting that her pain began with her vaccination. ECF No. 36 at 20-21. However, this evidence was not corroborated by way of affidavit or other means, accordingly while I have no reason to dispute the veracity of this evidence, I afford it substantially less weight.

When Petitioner's medical records are viewed as a whole, it is readily observable that Dr. Babaie's onset records are inconsistent with the onset records of every other provider with whom Petitioner treated for her shoulder injury. Beginning with orthopedist, Dr. Mazurek, who Petitioner saw on June 9, 2016 – a little more than three months after her vaccination – each subsequent provider's records describe the onset of Petitioner's injury as occurring on February 29, 2016 (the date of her vaccination), or "since" or concurrent with her Tdap vaccination. Ex. 13 at 3, 13; Ex. 14 at 6; Ex. 15 at 8, 11; Ex. 16 at 2; Ex. 17 at 4. This includes the contemporaneous records of two orthopedic offices, two physical therapy offices, and a chiropractic practice. Three of these five providers' onset histories were recorded within five months of Petitioner's February 29, 2016 vaccination and thus were also reasonably contemporaneous to the onset of Petitioner's pain. Ex. 13 at 3, 13; Ex. 14 at 6; Ex. 15 at 8, 11.

In sum, while the *most* contemporaneous records (Dr. Babaie's) do not support a finding of Table onset, I find that those records⁵ are outweighed (and outnumbered) by the consistent onset histories contained in Petitioner's subsequent treatment records – the most persuasive of which – are collectively dated within 128 days (or *less* than five months) of Petitioner's February 29, 2016 vaccination. Ex. 13 at 3, 13; Ex. 14 at 6; Ex. 15 at 8, 11. Onset in these later records is further corroborated by the declarations of Petitioner and the 12 other witness declarations offered in support of Petitioner's case. The fact that several of these treatment-related records were generated within five months of vaccination is also relevant to this inquiry; this is not a case where a petitioner relies on records long after the immediate timeframe to prove onset.

Thus, the totality of the evidence preponderantly supports the conclusion that Petitioner's shoulder pain occurred within 48 hours of her vaccination, and likely began the same day – February 29, 2016 – that her Tdap vaccination was administered.⁶ I reiterate, however, that this is an especially weak preponderant showing – enough to barely cross the "fifty percent and a feather" line, but not enough to fully remove all doubt that onset was possibly later. If it becomes necessary for me to determine damages in this matter, I will take into consideration the fact that Petitioner's alleged shoulder pain *is not documented in her medical records until nearly seven weeks following her vaccination*

⁵ Petitioner's February 29, 2016 Tdap vaccination was administered by Dr. Babaie's office and under her supervision. Ex. 10 at 1. Petitioner, in her Reply brief, argues that "it is possible and probable that Dr. Babaie did not include Petitioner's complaints about her shoulder pain stemming from the tetanus vaccination because she feared litigation since the vaccination was administered in her office." ECF No. 39 at 2-3. While this contention is not facially unreasonable, it does not find corroboration in the evidentiary record, and thus I do not deem it an *additional* reason to doubt the accuracy of Dr. Babaie's records-keeping.

⁶ While I have not specifically addressed every medical record, or all arguments presented in the parties' briefs, I have fully considered all records as well as arguments presented by both parties.

– indicating that Petitioner’s shoulder pain (even if reported to Dr. Babaie on March 15, 2016) was not severe enough to warrant mention close-in-time to vaccination, or to compel Petitioner to make an earlier medical appointment to address her shoulder pain. And the exacerbation of that pain was attributable to an independent injury in late April, by Petitioner’s own admission.

V. Scheduling Order

Respondent shall file a Supplemental Rule 4(c) Report, taking into consideration the above fact finding, by no later than Monday, May 25, 2022.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master